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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,211

02/02/2005

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43318-204165

2592

26694

7590

03/09/2009

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EXAMINER

KESSLER, CHRISTOPHER S

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

03/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,211	<b>Applicant(s)</b> ANDERSSON ET AL.	
	<b>Examiner</b> CHRISTOPHER KESSLER	<b>Art Unit</b> 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Responsive to the amendment filed 11 December 2008, claims 6-12 are amended, claim 13 is cancelled and claims 14-19 are added. Claims 6-12 and 14-19 are currently under examination.

### ***Status of Previous Rejections***

2. Responsive to the amendment filed 11 December 2008, new grounds of rejection are stated below.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "the machining." There is insufficient antecedent basis for this limitation in the claim. There is no mention of any machining in claim 6, and thus claim 18 does not particularly point out and describe what is being claimed.

Claim 19 recites the limitation "the titanium powder." There is insufficient antecedent basis for this limitation in the claim. There is no mention of any titanium in

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claim 6, and thus claim 19 does not particularly point out and describe what is being claimed.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over R. Rogier and F. Pernot, "Phosphate glass-ceramic-titanium composite materials," *Journal of Materials Science* **26** (1991) 5664-5670 (hereinafter "Rogier"), in view of WO 00/30788 (hereinafter "Troive").

Regarding claim 6, Rogier teaches the invention substantially as claimed. Rogier teaches a method of making a composite material for use in a prosthetic implant (see 1.Introduction). Rogier teaches that the method is used to produce a seal for the implant that will act as an intermediate layer between the core of the implant and a bioactive coating (see 1.Introduction), meeting the limitation of at least one surface or one portion, is arranged to be applied to bone and/or tissue in the human body, for example jaw bone, and which, at the surface or portion, is provided with an agent which stimulates bone growth. Rogier teaches wherein powders of a bone-compatible material (titanium) and an agent which stimulates bone growth (CAP) are mixed in

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powder form and compacted to form a composite (see 2.1 Base products and preparation of composites).

Rogier does not teach applying the mixture in a mold cavity belonging to a mold applied in a machine which effects impact compaction and which operates with a high impact compaction energy, activating the impacting unit of the machine so that it acts on the mold and transfers the energy to the powder mixture and thereby creates a blank for the device, and treating the blank in one or more treatment units for producing the device from the blank.

Troive teaches a method of consolidating powders (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that a powder is placed into a mold cavity in a mold applied in a machine which operates with a high impact compaction energy (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that the machine is activated and transfers energy to the powder to cause its compaction (see Abstract, Fig. 2, DETAILED DESCRIPTION).

Rogier and Troive do not teach wherein the blank is treated in one or more treatment units for producing the device from the blank. However, further processing steps would have been obvious to one of ordinary skill in the art at time of invention. For example, the seal material thus formed would be machined or cut to size for the prosthetic implant desired. The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

It would have been obvious to one of ordinary skill in the art at time of invention to have altered the method of Rogier by using the method of compaction and machine of Troive, because Troive teaches that the method is a fast and effective way of compacting powder (see pp. 5-6).

Regarding claim 7, The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

Regarding claim 10, Troive teaches wherein the machine is controlled so as to generate greater than 335 Nm of impact compaction energy (see p. 11).

7. Claims 6-12 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over A Bishop, et al., "A functionally gradient material produced by a powder metallurgical process," *Journal of Materials Science Letters* **13** (2003) 1516-1518 (hereinafter "Bishop"), in view of WO 00/30788 (hereinafter "Troive").

Regarding claim 6, Bishop teaches the invention substantially as claimed. Bishop teaches a method of making a composite material comprising hydroxyapatite in a titanium metal matrix (see p. 1516). Bishop teaches wherein the hydroxyapatite material is present to stimulate bone growth, and wherein the material is to be used for an implant prosthesis (see p. 1516), meeting the limitation of wherein at least one surface or one portion, is arranged to be applied to bone and/or tissue in the human body, for example jaw bone, and which, at the surface or portion, is provided with an agent which stimulates bone growth. Bishop teaches wherein the titanium powder and

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hydroxyapatite powder are mixed together and applied to a mold cavity belonging to a mold (see p. 1516).

Bishop does not teach applying the mixture in a mold cavity belonging to a mold applied in a machine which effects impact compaction and which operates with a high impact compaction energy, activating the impacting unit of the machine so that it acts on the mold and transfers the energy to the powder mixture and thereby creates a blank for the device, and treating the blank in one or more treatment units for producing the device from the blank.

Troive teaches a method of consolidating powders (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that a powder is placed into a mold cavity in a mold applied in a machine which operates with high impact compaction energy (see Abstract, Fig. 2, DETAILED DESCRIPTION). Troive teaches that the machine is activated and transfers energy to the powder to cause its compaction (see Abstract, Fig. 2, DETAILED DESCRIPTION).

Bishop and Troive do not teach wherein the blank is treated in one or more treatment units for producing the device from the blank. However, further processing steps would have been obvious to one of ordinary skill in the art at time of invention. For example, the seal material thus formed would be machined or cut to size for the prosthetic implant desired. The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

It would have been obvious to one of ordinary skill in the art at time of invention to have altered the method of Bishop by using the method of compaction and machine of Troive, because Troive teaches that the method is a fast and effective way of compacting powder (see pp. 5-6).

Regarding claim 7, Bishop in view of Troive does not teach that the material is treated after sintering as claimed. However, the steps of electropolishing and/or machining are well known in the art and would have been obvious to one of ordinary skill in the art at time of invention. The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

Regarding claim 8, Bishop teaches that titanium powder and hydroxyapatite powder are used, and that the titanium has a relatively small particle size (see p. 1516). Bishop further teaches that the HA particles have a particle size within the range of 72-118  $\mu\text{m}$  (see p. 1516), said range overlapping the range as claimed and establishing a prima facie case of obviousness for that range. It would have been obvious to one of ordinary skill in the art at time of invention to have used particles within the range as claimed, because Bishop teaches the same utility over an overlapping range. Applicant is further directed to MPEP 2144.05.

Regarding claim 9, Bishop teaches that in the mixing step, the mixture consists of 90% titanium powder and 10% hydroxyapatite powder (see p. 1516), meeting the limitation of "ca. 95% titanium powder and 5% HA powder." Bishop teaches that the



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powders are mixed together dry in a rotating mixer (see p. 1516), meeting the limitation of mixed in the dry state with agitation and stirring.

Regarding claim 10, Troive teaches wherein the machine is controlled so as to generate greater than 335 Nm of impact compaction energy (see p. 11).

Regarding claim 11, Bishop teaches that the particles are compressed to a substantial density, and that there is substantial surrounding of the HA particles (see pp. 1516-1517).

Regarding claim 12, Bishop teaches that the positions of the HA particles are controlled upon mixture and application in the mold cavity of the mold (see pp. 1516-1517). Bishop does not teach that the blank is machined so that HA particles are present at the surface exposed to the bone and/or tissue. The examiner takes Official Notice that it would have been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03. The machining thus taking place would have exposed HA particles to the surface exposed to the bone and/or tissue in order to allow bone ingrowth (see p. 1516).

Regarding claim 14, Bishop teaches to use hydroxyapatite (see p. 1516).

Regarding claim 15, Bishop teaches that the goal is to provide material suitable for implants (see p. 1516).

Regarding claim 16, the claim is a statement of intended use for the product made by the process. The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the

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[record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

In the instant case, the use of the device does not materially affect the method of making being claimed. Additionally, the fabrication of jaw bone implants is well known in the art, and would have been obvious to one of ordinary skill in the art at time of invention. The examiner takes Official Notice that it would have been obvious to have used the method of Bishop in the fabrication of a jaw bone implant, thus resulting in the use of the implant being applied to a jaw bone. Applicant is further directed to MPEP 2144.03.

Regarding claim 17, Bishop teaches to sinter titanium powder (see p. 1516).

Regarding claim 18, Bishop in view of Troive does not teach that the material is treated after sintering as claimed. However, the steps of electropolishing and/or machining are well known in the art and would have been obvious to one of ordinary skill in the art at time of invention. The examiner takes Official Notice that it would have

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been obvious to have cut or machined the material to size in order to use it in a prosthetic implant. Applicant is further directed to MPEP 2144.03.

Regarding claim 19, Bishop teaches that the powder is titanium powder. The percentage of purity of the titanium is not mentioned in Bishop. However, the purification of the titanium or the selection of a more pure form of titanium would have been obvious to one of ordinary skill in the art at time of invention. Applicant is further directed to MPEP 2144.04 VI.

### ***Response to Arguments***

8. Applicant's arguments filed 11 December 2008 have been fully considered but they are not persuasive.

Applicant argues that the combination of Troive and Rogier or Troive and Bishop does not teach the claimed invention because Rogier and Bishop teach a different kind of compaction method, respectively, and Troive teaches to compact cemented carbide material. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Bishop and Rogier are directed to powder metallurgy methods, as stated above, and one of ordinary skill would be motivated to improve those methods as stated above by applying the teachings of Troive.

Applicant argues that combination of Troive and Rogier or Troive and Bishop does not provide a reasonable expectation of success. However, applicant has provided no actual evidence that there would be no expectation of success, only argument. The fact that Bishop or Rogier do not mention other powder metallurgy methods is not a teaching that other powder metallurgy methods would be undesirable or unsuccessful. The examiner has already acknowledged that the compaction techniques of Rogier and Bishop (respectively) differ from that of Troive. However, one of ordinary skill in the art appreciates that the powder metallurgy compaction techniques of Rogier and Bishop (respectively) are analogous to the powder metallurgy compaction method of Troive. The motivation to apply the teachings of Troive is stated in the rejection above.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER KESSLER whose telephone number is (571)272-6510. The examiner can normally be reached on Mon-Fri, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy King/  
Supervisory Patent Examiner, Art  
Unit 1793

csk